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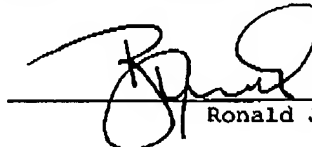
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MAY 17 2010

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE HONORABLE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No. : 10/762,530 Confirmation No. 5543
Applicant : Minoru SANO et al.
Filed : January 23, 2004
TC/A.U. : 3763
Examiner : Nathan R. Price
Dkt. No. : NPR-135
Cust. No. : 20374

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Ronald J. Kubovcik

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BRIEF ON APPEAL

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

May 17, 2010

Sir:

This is an appeal from the decision dated May 28, 2009, of
the primary Examiner finally rejecting claims 1 and 3 in this
application.

(i) REAL PARTY IN INTEREST

The real party in interest is Nipro Corporation, Osaka,
Japan.

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(ii) RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

(iii) STATUS OF CLAIMS

Claims 1 and 3 are pending in this application. Claims 2 and 4-8 have been cancelled. Claims 1 and 3 are appealed. Claims 1 and 3 as finally rejected appear in the attached Claims Appendix.

(iv) STATUS OF AMENDMENTS

No amendments were filed subsequent to the final rejection.

(v) SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 defines a prefilled syringe including a shoulder portion provided with a luer tip arranged to be connected to an injection needle at a tip thereof; a barrel closed by the shoulder portion and having an open proximal end; and a gasket inserted adjacent to the open proximal end of the barrel in a fluid-tight manner while being freely slidable, a medication being contained inside the barrel. (Specification, page 5, lines

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14-19; Fig. 1(a)).

The barrel has a multilayer structure in which an innermost layer and an outermost layer are both made of a polyolefin resin (specification, page 5, lines 20-21), and an intermediate layer is sandwiched by the innermost layer and the outermost layer and the intermediate layer is composed of at least one layer made of a resin excelling in an oxygen and/or water vapor barrier property (specification, page 5, lines 22-23; and page 7, lines 3-9).

The intermediate layer is formed up to a vicinity of a surface of the tip of the luer tip (specification, page 5, lines 24-26; and page 11, lines 5-12; Fig. 1(a) (see 11 and 11b)), and is not formed in a direction of the proximal end of the barrel from a proximal end of an initial insertion position of the gasket inserted in the barrel (specification, page 12, lines 3-6; Fig. 1(a) (see 30a (initial insertion position) and 10a (proximal end))).

Claim 3 defines a prefilled syringe which includes the elements of the prefilled syringe of claim 1 except that instead of being formed up to a vicinity of a surface of the tip of the luer tip, the intermediate layer in a cylindrical wall portion of the barrel is formed up to a rim of the shoulder portion; the

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shoulder portion formed with the polyolefin resin has a thickness sufficient to exert an oxygen and/or water vapor barrier property; and the luer tip is sealed by a cap having a barrier property. (Specification, page 6, lines 1-6; page 7, lines 3-9; and page 11, lines 18-23; Fig. 4 (see 97 (intermediate layer) and 83a (rim portion of a shoulder portion))).

(vi) GROUND OF REJECTION TO BE REVIEWED ON APPEAL

The ground of rejection to be reviewed on appeal is whether claims 1 and 3 are unpatentable under 35 U.S.C. § 103(a) over Reinhard et al., U.S. Patent No. 6,331,174 ("Reinhard"), in view of Kaufhold, Jr. et al., U.S. Patent No. 5,125,898 ("Kaufhold").

(vii) ARGUMENT

Reinhard is cited by the Examiner as disclosing a syringe which meets all of the elements of claims 1 and 3, except that the syringe of Reinhard does not include a Luer tip or an intermediate layer composed of at least one layer made of resin. (Final Action dated May 28, 2009, page 3, lines 5-6 from the bottom of the page). The Examiner identifies Kaufhold as teaching the use of a Luer tip in combination with a syringe body.

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The conclusion of the Examiner is that it would have been obvious to a person of ordinary skill in the art to modify the syringe of Reinhard to include a Luer tip "for the purpose of providing a well-known attachment mechanism commonly used in the art of syringes and injectors to provide sufficient structure for attachment of a needle (abstract)." (Final Action, page 3, last line, to page 4, line 2). The use of a resin as an intermediate layer is stated in the Final Action to be obvious "since it has been held to be within the general skill of a worker in the art to select a known material on the basis for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416." (Final Action, page 4, lines 6-8).

The proposed modification of the syringe of Reinhard to include a luer tip is improper as a matter of law.

The invention of Reinhard is a prefilled, disposable syringe that overcomes the problems and disadvantages of disposable syringes of the prior art. One of the prior art disposable syringes identified in Reinhard is that disclosed in U.S. Patent No. 4,861,335. The disposable syringe disclosed in U.S. Patent No. 4,861,335 includes a luer tip. (Note the description of the prior art syringe in Col. 2, lines 17-19, of Reinhard: "The hypodermic needle is fastened to the cap by means of a mounting

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method known under the brand name LUER-LOCK. Therefore, the needle is not integrated with the nozzle.").

In light of the prior art described therein, Reinhard discloses, as the object of its invention, the providing of a prefilled syringe that can be manufactured as a preassembled unit "consisting of a barrel with an integrated needle ...". (Col. 2, lines 42-43). (Emphasis appellant's). To accomplish this objective, the nozzle area of the disposable syringe of Reinhard is especially constructed to encase the needle. (See, for example, Col. 3, lines 31-37:

"One development of the disposable syringe in this invention lies in the nozzle area where the hypodermic needle is fastened. The nozzle is constructed to encase the needle, which has an advantage over known finished glass syringes with a glued-in needle, so that no adhesive can interact with the preparation. This is especially important for highly sensitive preparations.")

The proposed modification of the prefilled syringe of Reinhard to include a needle not integrated with the nozzle is contrary to and will destroy the invention on which Reinhard is based.

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It has been held by the Office that references cannot be properly combined if the effect would destroy the invention on which one of the references is based. *Ex parte Hartmann*, 186 USPQ 366 (BdPatApp&Int 1974).

For this reason, the final rejection of the Primary Examiner is improper as a matter of law and should be reversed.

Appellant respectfully requests that the final rejection of the primary Examiner be reviewed and reversed.

The fee of \$540.00 for this appeal brief is included in Form PTO-2038 which is submitted herewith. Please charge any additional required fees or credit any overpayment to Deposit Account No. 111833.

Respectfully submitted,

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(viii) CLAIMS APPENDIX

1. A prefilled syringe comprising: a shoulder portion provided with a luer tip arranged to be connected to an injection needle at a tip thereof; a barrel closed by the shoulder portion and having an open proximal end; and a gasket inserted adjacent to the open proximal end of the barrel in a fluid-tight manner while being freely slidable, a medication being contained inside the barrel, wherein

the barrel has a multilayer structure in which an innermost layer and an outermost layer are both made of a polyolefin resin, and an intermediate layer is sandwiched by the innermost layer and the outermost layer and the intermediate layer is composed of at least one layer made of a resin excelling in an oxygen and/or water vapor barrier property,

and further wherein the intermediate layer is formed up to a vicinity of a surface of the tip of the luer tip, and is not formed in a direction of the proximal end of the barrel from a proximal end of an initial insertion position of the gasket inserted in the barrel.

3. A prefilled syringe comprising: a shoulder portion provided with a luer tip arranged to be connected to an injection needle at a tip thereof; a barrel closed by the shoulder portion and having an open proximal end; and a gasket inserted adjacent to the open proximal end of the barrel in a fluid-tight manner

while being freely slidable, a medication being contained inside the barrel, wherein

the barrel has a multilayer structure in which an innermost layer and an outermost layer are both made of a polyolefin resin, and an intermediate layer is sandwiched by the innermost layer and the outermost layer and the intermediate layer is composed of at least one layer made of a resin excelling in an oxygen and/or water vapor barrier property,

and further wherein:

an end of the intermediate layer in a cylindrical wall portion of the barrel is formed up to a rim of the shoulder portion;

the shoulder portion formed with the polyolefin resin has a thickness sufficient to exert an oxygen and/or water vapor barrier property; and

the luer tip is sealed by a cap having a barrier property.

(ix) EVIDENCE APPENDIX

None

(x) RELATED PROCEEDINGS APPENDIX

None